

Trends on Rhinosinusitis Diagnosis and Treatment

Aktualne kierunki diagnostyki i leczenia zapalenia zatok przynosowych

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SUMMARY

A growing interest in rhinosinusitis in recent years resulted in two European Position Papers in Rhinosinusitis and Nasal Polyposis (EP3OS) documents, published in 2005 and 2007, respectively. The latter is intended to be a state-of-the-art review for specialists and general practitioners, updating the current knowledge on rhinosinusitis and nasal polyposis, proposing the guidance for definitions and outcome measurements in research and providing an evidence-based review of the available treatments. The present article briefly discusses the guidelines for acute rhinosinusitis (ARS) and chronic rhinosinusitis (CRS) diagnoses, as well as treatment recommendations provided by that document. Recent, epidemiological PROSINUS study of ARS, carried out in Spain, is also briefly reviewed, with special emphasis on Cyclamen europaeum extract use in ARS treatment. A new treatment approach is proposed, based on Cyclamen europaeum extract use in ARS and in the postoperative management of patients with CRS and nasal polyps undergoing endoscopic sinus surgery, which is associated with clinically confirmed, significant improvement of patients' symptoms, nasal endoscopic signs and patient satisfaction in comparison to saline. These results are thought to be connected with nasal drainage-facilitating and paranasal sinuses-cleaning activities of the extract.

Hasła indeksowe: leczenie zapalenia zatok przynosowych, wytyczne EP3OS, ekstrakt *Cyclamen europaeum*

Keywords: rhinosinusitis treatment, EP3OS guidelines, *Cyclamen europaeum* extract

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Introduction

Rhinosinusitis is a significant and increasing health problem which results in a large financial burden on society. The first European Position Paper in Rhinosinusitis and Nasal Polyposis (EP3OS) was published in 2005, simultaneously in the ENT and allergy literature. In the intervening couple of years an impressive number of high quality studies had been published looking at both the pathophysiology and treatment of the conditions and this resulted in the latest iteration of EP3OS in 2007 [1]. This EP3OS pocket guide offers evidence-based recommendations on its diagnosis and treatment while the EP3OS full document on which this is based is intended to be a state-of-the-art review for the specialist as well as for the general practitioner: a) to update their knowledge of rhinosinusitis and nasal polyposis; b) to provide an evidence-based documented review of the diagnostic methods; c) to provide an evidence-based review of the available treatments; d) to propose a stepwise approach to the management of the disease; and e) to propose guidance for definitions and outcome measurements in research in different settings. The severity of disease may be assessed by total VAS score (0 to 10 cm): mild (0 a 3), moderate (>3 a 7), and severe (>7 a 10) [1, 2].

Acute Rhinosinusitis (ARS)

Diagnosis is based on symptoms and imaging is not recommended except in case of severe disease, immunocompetent patients, and signs of complications. ARS is defined as a sudden onset of at least two symptoms, one of them being nasal congestion/obstruction/blockage or anterior/posterior nasal discharge, and facial pressure/pain or decrease/loss of smell [1, 3]. In common cold (mild ARS) symptoms last for less than 10 days while in moderate and severe (fever, unilateral severe facial pain) ARS symptoms may increase after 5 days or last for more than 10 days, but always for less than 12 weeks. Treatment of common cold is only symptomatic, while nasal corticosteroids in monotherapy (moderate) or with oral antibiotics (severe) are recommended in ARS [3, 4].

Chronic Rhinosinusitis (CRS) and nasal polyps

CRS, including nasal polyps, are defined as an inflammation of the nose and paranasal sinuses with at least two symptoms, one of them being nasal congestion/obstruction/blockage or anterior/posterior nasal discharge, and facial pressure/pain or decrease/loss of

smell, lasting for more than 12 weeks [6]. In addition, diagnosis may be confirmed by nasal endoscopy (nasal polyps or mucopurulent discharge) and/or CT scan (mucosal abnormality in the sinuses or ostiomeatal complexes) [1, 3]. The treatment of CRS is based on the use of saline nasal lavages and long term nasal corticosteroids, either in spray (mild) or drops (moderate). In severe nasal polyps short courses of oral corticosteroids are also recommended. Endoscopic sinus surgery shall be performed only when medical treatment fails while optimal medical treatment should always be continued after surgery [3, 4, 5, 6].

The Prosinus study

An epidemiological study on ARS has been recently performed in Spain with the following conclusions are: 1) ARS symptoms are predominantly of moderate to severe intensity with a significant impact on patient's quality of life; 2) in the diagnosis, plain sinus x-ray are overused by both GPs and ENT specialists; 3) in the treatment, ENT specialists use less antibiotics and mucolytics than GPs; 4) the disease is cured in 83% of the cases within 4 weeks of treatment (mean: 13.7 days); 5) Cyclamen europeum increases the cure rate of ARS when used both on top of other treatments or in monotherapy; and 5) the socioeconomic impact of ARS in the Spain is very high with a cost of 795 € per episode and 700 to 1,400 million € per year.

A new treatment approach

In the treatment of rhinosinusitis, a cleaning process is needed to improve the recovery of the nasal mucosa and to avoid postoperative complications. The lyophilized extract of *Cyclamen europeum* nasal spray is a new treatment that facilitates physiological drainage and cleaning of the paranasal sinuses through the mucous membranes. To date, three clinical trials have been conducted in Germany and the USA to evaluate the efficacy and safety of this product in monotherapy or adjunctive therapy with antibiotics in patients diagnosed of moderate to severe ARS and in the postoperative evolution of patients with CRS and nasal polyps undergoing endoscopic sinus surgery. The design was randomized, double-blind, placebo-controlled (ARS) or single-blind controlled with saline (CRS). Outcome measurements were: reported symptoms, mucopurulent secretion (nasal endoscopy), sinus occupancy (CT scan), patient and investigator satisfaction, and

safety evaluation (adverse events). In the ARS study (Germany), *Cyclamen* showed a statistical improvement in facial pain, endoscopic signs, and both patient and investigator satisfaction compared to placebo. Similarly, in the USA trial, *Cyclamen* treatment resulted in a significant improvement in Total Symptom Score and sinus occlusion (CT scan), compared to baseline. In the CRS post-operative study (Germany), *Cyclamen* showed a statistical improvement of endoscopic signs compared to saline, and a similar improvement than saline in nasal symptoms and in both investigator and patient satisfaction. There were no safety concerns and unexpected adverse events with *Cyclamen*. In conclusion, *Cyclamen europeum* is a new approach to the treatment of ARS and in the postoperative management of patients with CRS and nasal polyps undergoing endoscopic sinus surgery.

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